DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-829/S009, S-011
NDA 9-830/S-010,S-012
NDA 11-665/S-013, S-015
NDA 15-193/S-018

ICN Pharmaceuticals, Inc
Attention: Anil Hiteshi
Senior Manager, Corporate Regulatory Affairs
3300 Hyland Avenue
Costa Mesa, CA 92626
USA

Dear Mr. Hiteshi:

Please refer to your new drug applications for Mestinon Tablets, Mestinon Timespan Tablets, Mestinon Syrup, and Mestinon Injection.

Reference is also made to the following supplemental applications and amendments:

NDA	Supplement	Letter Date	Date Received
9-829	009	February 9, 1994	February 18, 1994
9-829	009 (amended)	July 21, 1994	July 26, 1994
9-830	010	November 20, 1995	December 01, 1995
9-830	012	October 27, 1998	October 30, 1998
11-665	013	February 9, 1994	February 18, 1994
11-665	013 (amended)	July 21, 1994	July 26, 1994
11-665	015	November 20, 1995	December 01, 1995
15-193	018	November 20, 1995	December 01, 1995

These supplemental new drug applications provide for the following:

NDA 9-829/S-009 & NDA 11-665/S-013
These supplements provide for attachment of a sticker to the cap of every bottle of Mestinon Tablets and Mestinon Timespan Tablets stating, “CAUTION: EXTREMELY MOISTURE SENSITIVE. DO NOT REMOVE DESICCANT. CLOSE TIGHTLY.”

NDA 9-829/S-011,NDA 9-830/S-010, NDA 11-665/S-015, & NDA 15-193/S-018
These supplements provide for the addition of a PRECAUTION section to labeling, the addition of the structural formula to the DESCRIPTION section of labeling, and the addition of three references.

NDA 9-830/S-012
This supplemental application provides for the addition of the Pediatric Use subsection to the PRECAUTIONS section of labeling.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling (identified as 13-06-74703-0995 & 13-20-74703-0995) submitted on November 20, 1995 for NDA 9-829, NDA 11-665, NDA 15-193 and the final printed labeling submitted October 27, 1998 (label identified as 13-06-74725-1098)for NDA 9-830. Accordingly, these supplemental applications are approved effective the date of this letter.

Labeling changes of the kind which you have proposed under the supplemental applications are permitted by section 314.70 (c) of the regulations to be instituted prior to approval of these supplements. It is understood that the changes, described in the above NDA supplements, have been made.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirement for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
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